



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

MV

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,646	03/24/2005	Takaaki Terahara	7388/84281	8337
42798 7590 02/12/2007 FITCH, EVEN, TABIN & FLANNERY P. O. BOX 18415 WASHINGTON, DC 20036			EXAMINER FITZGERALD, MARC C	
			ART UNIT	PAPER NUMBER
			1615	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/12/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/525,646

Applicant(s)

TERAHARA ET AL.

Examiner

Marc C. Fitzgerald

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2/25/05; 3/18/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application

Receipt is acknowledged of correspondences received on 10 May 2005 in the matter of U.S. Patent Application No. 10/525,646. Claims included in the prosecution are 1-6.

Information Disclosure Statement

The information disclosure statement (IDS) filed on 25 February 2005 and 18 March 2005 fail to comply with 37 CFR 1.97, 1.98, and MPEP § 609, which require a concise explanation of relevance or English-language translation of any non-English language documents cited on the IDS. The IDS lists both English and non-English documents. Although all documents have been placed in the application file, only those documents in English have been considered.

Claim Rejection(s) – 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

Art Unit: 1615

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Nos. 6,495,159 to Hirano et al. in view of US 2004/0028724 A1 to Terahara et al.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Instant claim 1 is a composition claim directed toward a patch comprising a backing layer and adhesive layer wherein a drug and an adhesive base agent are disposed on the backing layer and the adhesive base agent comprises styrene-isoprene-styrene block, 2-ethylhexyl acrylate-vinyl acetate copolymer and a basic nitrogen including polymer. Examples 1, 6, and 8 in US '159 disclose an adhesive preparation that comprises a drug, styrene-isoprene-styrene block copolymer, 2-ethylhexyl acrylate-vinyl acetate copolymer, and a basic nitrogen-including polymer. Polyisobutylene as exemplified in the examples qualifies as basic nitrogen-including polymer having no adhesion property at normal temperature.

Instant claim 3 requires that the solubility of the drug be less than 1%. Example 1 reads on the requirements of instant claim 3 wherein 3.0 wt. % of ondasetron hydrochloride is in 40.0 wt. % of buffer water. Resolving the math indicates that the solubility of the drug with respect to water would be less 1%.

Instant claim 5 is dependent from claim 1 and further comprises an organic acid. Example 1 discloses dibutyl hydroxytoluene. Dibutyl hydroxytoluene is an organic acid and meets the organic acid limitation.

Instant claim 6 is dependent from claim 1 and further comprises a tackifier. Example 1 discloses alicyclicsaturated hydrocarbon resin. Alicyclicsaturated hydrocarbon resin is a tackifier and meets the tackifier limitation. Examples 1, 6, and 8 teach the invention claimed in instant claims 1, 3, 5, and 6.

The basic requirements of the invention as detail in Instant claim 1 are met with US '159. The selection of the specific nitrogen-including polymer appears to be a matter of preference. However, it was known at the time of invention per the art of US '157 that polyvinyl acetal diethylamino acetate and methyl methacrylate-butyl methacrylate-dimethyl-aminoethyl methacrylate or polyvinyl acetal diethylamino acetate (commercially available as Eudragit E, Rohm GmbH) where effective nitrogen-including polymers in transdermal adhesives with specific utility in transdermal adhesives comprising styrene-isoprene-styrene block copolymer and 2-ethylhexyl acrylate-vinyl acetate copolymer. See claim 1, 5, and 10 of US '724.

Instant claim 4 requires that the drug is selected from a group comprising pergolide. At [0022] and in Example 5 of US '724, Terahara teaches the transdermal

Art Unit: 1615

delivery of pergolide and pergolide mesylate, respectively. The selection of drug for use in the patch appears to be a matter of therapeutic preference. Therefore it would be reasonable to conclude that one of ordinary skill in the art at the time of the invention could modify the invention of '159 with the teachings of '724 to obtain the instant invention. The artisan would have been motivated to do so to obtain the specific therapeutic benefits of the drug being administered transdermally. The combined teachings of US '724 and '159 make *prima facie* obvious the instant application.

Correspondences

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marc C. Fitzgerald whose telephone number is (571) 272-8510. The examiner can normally be reached between 9:30 AM - 6:30 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marc C. Fitzgerald
Art Unit -1615



8 January 2007



MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600